

## **WHAT IS CLAIMED IS:**

1. An orthopedic knee brace for controlling movement of a wearer's knee comprising:

a thigh engaging member;

a calf engaging member; and

one or more hinges selected from a hinge lateral to the wearer's knee connecting said thigh engaging member to said calf engaging member, or a hinge medial to the wearer's knee connecting said thigh engaging member to said calf engaging member, wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom between a femur and a tibia during flexion and extension of a wearer's leg.

2. The orthopedic knee brace of claim 1, which includes a hinge lateral to the wearer's knee, connecting said thigh engaging member to said calf engaging member and a hinge medial to the wearer's knee, connecting said thigh engaging member to said calf engaging member, wherein said thigh engaging member is rigid and said calf engaging member is rigid and said thigh engaging member and said calf engaging member form rigid connections to said lateral hinge and said medial hinge, whereby said rigid connections facilitate the function of said knee brace to actively prescribe asymmetric three-dimensional anatomic motion between a femur and a tibia during flexion and extension of a wearer's leg.

3. The orthopedic knee brace of claim 1, wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom by actively prescribing flexion and extension, abduction and adduction, internal/external rotation, anterior/posterior translation, medial/lateral translation, and proximal/distal translation between a femur and a tibia of a wearer's leg.

4. The orthopedic knee brace of claim 2, further comprising:

an upper lateral hinge linkage forming said rigid connection between said thigh engaging member and said lateral hinge;

a lower lateral hinge linkage forming said rigid connection between said calf engaging member and said lateral hinge;

an upper medial hinge linkage forming said rigid connection between said thigh engaging member and said medial hinge;

a lower medial hinge linkage forming said rigid connection between said calf engaging member and said medial hinge.

5. The orthopedic knee brace of claim 2 wherein said lateral hinge and said medial hinge further comprise a plurality of parallel, concentric, spherical shells; and a plurality of cam follower pins and a plurality of cam slots distributed among said shells, wherein said plurality of cam follower pins engage said plurality of cam slots to rotatably engage said shells, and wherein a side of each of said cam follower pins is shaped to track a path parallel to a side of each of said cam slots in which said pin is engaged.

6. The orthopedic knee brace of claim 5, wherein said side of said cam follower pin at a point closest to said cam slot is parallel to said side of said cam slot throughout the range of motion from flexion to extension of said knee brace.

7. The orthopedic knee brace of claim 6, wherein said side of said cam follower pin at the point closest to said cam slot forms an angle to a radial axis of said spherical shell.

8. The orthopedic knee brace of claim 7, wherein said angle is between approximately 0 and 45 degrees.

9. The orthopedic knee brace of claim 5, further comprising an extension stop member attached to said hinge to limit flexion and extension of the tibia relative to the femur of the wearer's leg.

10. The orthopedic knee brace of claim 9, wherein said extension stop member limits extension of the tibia relative to the femur to a minimum flexion angle between approximately 0 degrees and approximately 20 degrees.

11. The orthopedic knee brace of claim 4, wherein said thigh engaging member comprises a medial portion, a lateral portion and an anterior portion, and said calf

engaging member comprises a medial portion, a lateral portion and an anterior portion, said medial portion of said thigh engaging member is rigidly attached to said upper medial linkage, said lateral portion of said thigh engaging member is rigidly attached to said upper lateral linkage, said medial portion of said calf engaging member is rigidly attached to said lower medial linkage, and said lateral portion of said calf engaging member is rigidly attached to said lower lateral linkage.

12. The orthopedic knee brace of claim 2 further comprising:

attachment means on said thigh engaging member to attach said thigh engaging member to a wearer's thigh;

attachment means on said calf engaging member to attach said calf engaging member to a wearer's calf.

13. The orthopedic knee brace of claim 2, wherein each of said thigh engaging member and said calf engaging member has a unitary construction.

14. The orthopedic knee brace of claim 13, wherein said unitary construction is molded construction or laminated single body construction.

15. The orthopedic knee brace of claim 5 wherein said lateral hinge has a first variable axis of rotation and comprises:

a first shell, a second shell, and a third shell in the shape of a segment of a sphere, said first and third shells being concentric and fastened parallel to each other to form a first opening, said first and third shells being fastened to one of said lateral portion of said thigh engaging member and said calf engaging member, said second shell having a first end designed to be inserted into said first opening and a second end fastened to the other of said lateral portion of said thigh engaging member and said calf engaging member, said first and third shells rotatably engaged to said second shell by said plurality of cam follower pins and said plurality of cam slots, wherein said medial hinge has a second variable axis of rotation and comprises a fourth shell, a fifth shell, and a sixth shell in the shape of a segment of a sphere, said fourth and sixth shells being concentric and fastened parallel to each other to form a second opening, said fourth and sixth shells being fastened to one of said medial portion of said thigh engaging member and said calf engaging

member, said fifth shell having a first end designed to be inserted into said second opening and a second end fastened to the other of said medial portion of said thigh engaging member and said calf engaging member, said fourth and sixth shells rotatably engaged to said fifth shell by said plurality of cam follower pins and said plurality of cam slots, whereby, in use, when the wearer's leg is extended, said first variable axis of rotation and said second variable axis of rotation are coincident and in alignment with the wearer's condyles, and wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom by actively prescribing flexion and extension, abduction and adduction, internal/external rotation, anterior/posterior translation, medial/lateral translation, and proximal/distal translation between a femur and a tibia of the wearer's leg.

16. The orthopedic knee brace of claim 15, wherein said medial hinge and said lateral hinge have concave surfaces facing the knee.

17. The orthopedic knee brace of claim 15, wherein said lateral hinge further comprises a first cam follower pin and second cam follower pin distributed among said shells and extending inside said first opening, said first pin located on said second shell and said second pin located on said third shell, and a first cam slot and a second cam slot distributed among said shells to receive said first and second pins, respectively, said first shell comprising said first cam slot and said second shell comprising said second cam slot, and wherein said medial hinge further comprises a third cam follower pin and a fourth cam follower pin distributed among said shells and extending inside said second opening, said third pin located on said fifth shell and said fourth pin located on said sixth shell, and a third cam slot and a fourth cam slot distributed among said shells to receive said third and fourth pins, respectively, said third shell comprising said third slot and said fourth shell comprising said fourth slot.

18. The orthopedic knee brace of claim 15, wherein said first and third shells further comprise a lateral inside shell and a lateral outside shell, said lateral inside shell having a first extension fastened to said lateral portion of said thigh engaging member, said lateral outside shell having a second extension fastened to said lateral portion of said thigh engaging member, said second shell having a third extension fastened to said lateral portion of said calf engaging member, and wherein said fourth and sixth shells further comprise a medial inside shell and a medial outside shell, said medial inside shell having a fourth extension fastened to said medial portion of said thigh engaging member, said

medial outside shell having a fifth extension fastened to said medial portion of said thigh engaging member, said fifth shell having a sixth extension fastened to said medial portion of said calf engaging member.

19. The orthopedic knee brace of claim 18, wherein said first and third extensions are rigidly fastened to said thigh engaging member, and wherein said second and fourth extensions are rigidly fastened to said calf engaging member.

20. The orthopedic knee brace of claim 15, wherein said first, second and third shells have a spherical surface defining a first radius, and said fourth, fifth, and sixth shells have a spherical surface defining a second radius.

21. The orthopedic knee brace of claim 20, wherein said first radius is in a range from approximately 2.5 inches to 3.5 inches.

22. The orthopedic knee brace of claim 20, wherein said second radius is in a range from approximately 1.5 inches to 2.5 inches.

23. The orthopedic knee brace of claim 2 wherein said substantially rigid thigh engaging member and said substantially rigid calf engaging member are composed of a reinforced fiber filled thermoplastic resin.

24. The orthopedic knee brace of claim 2 wherein said lateral hinge and said medial hinge are composed of a metal.

25. The orthopedic knee brace of claim 24, wherein said lateral hinge and said medial hinge are composed of aluminum.

26. The orthopedic knee brace of claim 2 wherein said substantially rigid thigh engaging member and said substantially rigid calf engaging member are composed of a composite of reinforced fiber filled thermoplastic resin and metal.

27. The orthopedic knee brace of claim 2 wherein said lateral hinge and said medial hinge are composed of a composite of reinforced fiber filled thermoplastic resin and metal.

28. The orthopedic knee brace of claim 2 wherein said substantially rigid thigh engaging member and said substantially rigid calf engaging member have an elliptical cross sectional shape.

29. A method of constructing an orthopedic knee brace, comprising:

constructing a thigh engaging member and a calf engaging member from a rigid material;

connecting said thigh engaging member to said calf engaging member with a lateral hinge and a medial hinge;

holding said lateral hinge and said medial hinge at a fixed distance along an instantaneous axis of rotation of the wearer's knee; and

adjusting a distance between said lateral hinge and said medial hinge to fit a pin/slot geometry whereby said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom by actively prescribing flexion and extension, abduction and adduction, internal/external rotation, anterior/posterior translation, medial/lateral translation and proximal/distal translation between a femur and a tibia of a wearer's leg.

30. An anatomical bracing hinge for an orthopedic knee brace comprising:

a medial hinge including a first shell, a second shell, and a third shell in the shape of a segment of a sphere, said first and third shells being concentric and fastened parallel to each other to form a first opening, said first and third shells being fastened to one of a medial portion of a thigh engaging member and a calf engaging member, said second shell being fastened to the other of said medial portion of said thigh engaging member and said calf engaging member, said second shell designed to be inserted into said first opening concentric and parallel to said first and third shells, said first and third shells rotatably engaged to said second shell by a plurality of cam follower pins engaging a plurality of cam slots; and

a lateral hinge including a fourth shell, a fifth shell, and a sixth shell in the shape of a segment of a sphere, said fourth and sixth shells being concentric and fastened parallel to each other to form a second opening, said fourth and sixth shells being fastened to one of a lateral portion of a thigh engaging member and a calf engaging member, said fifth shell being fastened to the other of said lateral portion of said thigh engaging member and said calf engaging member, said fifth shell designed to be inserted into said second opening concentric and parallel to said fourth and sixth shells, said fourth and sixth shells rotatably engaged to said fifth shell by a plurality of cam follower pins engaging a plurality of cam slots, wherein said knee brace accurately prescribes asymmetric three-dimensional anatomic motion between a femur and a tibia during flexion and extension of a wearer's leg.

31. The anatomical bracing hinge of claim 30, wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom by actively prescribing flexion and extension, abduction and adduction, internal/external rotation, anterior/posterior translation, medial/lateral translation and proximal/distal translation between a femur and a tibia of a wearer's leg.

32. The anatomical bracing hinge of claim 28, wherein said first, second, and third shells have a concave surface facing the medial side of a wearer's knee, and said fourth, fifth, and sixth shells have a concave surface facing the lateral side of a wearer's knee.

33. The anatomical bracing hinge of claim 30, wherein said anatomical bracing hinge incorporated within an orthopedic knee brace exhibits a variable axis of rotation coincident and in alignment with a wearer's femoral condyles, and wherein said brace actively prescribes flexion and extension, abduction and adduction, internal-external rotation, anterior/posterior translation, medial/lateral translation and proximal/distal translation between a femur and a tibia of a wearer's leg.

34. The anatomical bracing hinge of claim 30, wherein a side of said cam follower pin is shaped to track a path parallel to a side of said cam slot.

35. The anatomical bracing hinge of claim 34, wherein said side of said cam follower pin at a point closest to said cam slot is parallel to said side of said cam slot throughout the range of motion from flexion to extension of said knee brace.

36. The anatomical bracing hinge of claim 35, wherein said side of said cam follower pin at the point closest to said cam slot forms an angle to a radial axis of said spherical shell.

37. The anatomical bracing hinge of claim 36, wherein said angle is between approximately 0 and 45 degrees.

38. An orthopedic knee brace for controlling movement of a wearer's knee comprising:

a thigh engaging means;

a calf engaging means;

a first interengaging control means lateral to the wearer's knee for rotatably connecting said thigh engaging means to said calf engaging means; and

a second interengaging control means medial to the wearer's knee for rotatably connecting said thigh engaging means to said calf engaging means, wherein said thigh engaging means is substantially rigid and forms rigid connections between said thigh engaging means and said first interengaging control means and between said thigh engaging means and said second interengaging control means, and wherein said calf engaging means is substantially rigid and forms rigid connections between said calf engaging means and said first interengaging control means and between said calf engaging means and said second interengaging control means, whereby said rigid connections facilitate a function of said knee brace to accurately prescribe flexion and extension, abduction and adduction, internal-external rotation, anterior/posterior translation, medial/lateral translation and proximal/distal translation between a femur and a tibia during flexion and extension of a wearer's leg.

39. An orthopedic knee brace for controlling movement of a wearer's knee comprising:

a thigh engaging member;

a calf engaging member; and

a unilateral hinge selected from a hinge lateral to the wearer's knee connecting said thigh engaging member to said calf engaging member, or a hinge medial to the wearer's knee connecting said thigh engaging member to said calf engaging member, wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom between a femur and a tibia during flexion and extension of a wearer's leg.

40. The orthopedic knee brace of claim 39, wherein said knee brace is effective for treatment and relief of symptoms of osteoarthritis in a wearer's knee

41. The orthopedic knee brace of claim 39, further wherein said unilateral hinge is a lateral hinge.

42. The orthopedic knee brace of claim 39, wherein said unilateral hinge is a medial hinge.

43. The orthopedic knee brace of claim 39, wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom by actively prescribing flexion and extension, abduction and adduction, internal/external rotation, anterior/posterior translation, medial/lateral translation, and proximal/distal translation between a femur and a tibia of a wearer's leg.

44. The orthopedic knee brace of claim 39, further comprising:

an upper lateral hinge linkage forming a connection between said thigh engaging member and said lateral hinge; and

a lower lateral hinge linkage forming a connection between said calf engaging member and said lateral hinge.

44. The orthopedic knee brace of claim 39, further comprising:

an upper medial hinge linkage forming a connection between said thigh engaging member and said medial hinge;

a lower medial hinge linkage forming a connection between said calf engaging member and said medial hinge.

45. The orthopedic knee brace of claim 39 wherein said hinge comprises a plurality of parallel, concentric, spherical shells; and a plurality of cam follower pins and a plurality of cam slots distributed among said shells, wherein said plurality of cam follower pins engage said plurality of cam slots to rotatably engage said shells, and wherein a side of each of said cam follower pins is shaped to track a path parallel to a side of each of said cam slots in which said pin is engaged.

46. The orthopedic knee brace of claim 39, wherein said side of said cam follower pin at a point closest to said cam slot is parallel to said side of said cam slot throughout the range of motion from flexion to extension of said knee brace.

47. The orthopedic knee brace of claim 46, wherein said side of said cam follower pin at the point closest to said cam slot forms an angle to a radial axis of said spherical shell.

48. The orthopedic knee brace of claim 47, wherein said angle is between approximately 0 and 45 degrees.

49. The orthopedic knee brace of claim 45, further comprising an extension stop member attached to said hinge to limit flexion and extension of the tibia relative to the femur of the wearer's leg.

50. The orthopedic knee brace of claim 39 further comprising:

attachment means on said thigh engaging member to attach said thigh engaging member to a wearer's thigh;

attachment means on said calf engaging member to attach said calf engaging member to a wearer's calf.

51. The orthopedic knee brace of claim 39, further comprising a dynamic force strap attaching said thigh engaging member and said calf engaging member to the wearer's leg, wherein force is transmitted to a wearer's thigh, calf and knee for treatment and relief of symptoms of osteoarthritis in a wearer's knee.

52. The orthopedic knee brace of claim 39, wherein said hinge is a lateral or medial hinge having a variable axis of rotation and comprising a first shell, a second shell,

and a third shell in the shape of a segment of a sphere, said first and third shells being concentric and fastened parallel to each other to form an opening, said first and third shells being fastened to one of said lateral portion of said thigh engaging member and said calf engaging member; said second shell having a first end designed to be inserted into said opening and a second end fastened to the other of said lateral portion of said thigh engaging member and said calf engaging member, said first and third shells rotatably engaged to said second shell by said plurality of cam follower pins and said plurality of cam slots, whereby, in use, when the wearer's leg is extended, said variable axis of rotation is in alignment with the wearer's condyles; and wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom by actively prescribing flexion and extension, abduction and adduction, internal/external rotation, anterior/posterior translation, medial/lateral translation, and proximal/distal translation between a femur and a tibia of the wearer's leg.

53. The orthopedic knee brace of claim 39, wherein said hinge has a concave surface facing the knee.